UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/158,120	09/21/98	JOHNSON L	469201-367

EXAMINER	
EWOLDT,G	
ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 01/16/01

HM22/0116

ELLIOT M OLSTEIN
CARELLA BYRNE BAIN GILFILLAN
CECCHI STEWART & OLSTEIN
6 BECKER FARM ROAD
ROSELAND NJ 07068

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/158,120	Johnson, L.
Examiner	**Group Art Unit**
Gerald Ewoldt	1644

☒ Responsive to communication(s) filed on *Oct 30, 2000*.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4, 6, 7, 10, 13, 21, and 22* is/are pending in the application.

Of the above, claim(s) *10, 13, and 22* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 6, 7, and 21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Claims 1-4, 6-7, and 21 are being acted upon.

2. In view of the remarks, arguments, and terminal disclaimer, filed 10/30/00, only the following rejections remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 6 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that, other than antibodies encoded by SEQ IDS NO:17 and 20 (humanized mAb 1308F) and 31 and 34 (humanized mAb 1129), both of which are specific for site C of the respiratory syncytial virus (RSV) protein F, Applicant was in possession of an antibody specific for antigenic site A of RSV protein F. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

Applicant's arguments, filed 10/30/00, have been fully considered but they are not persuasive. Applicant argues that because a human-murine antibody has been made to the RSV F antigen C site, an antibody could be made to the A site as well. Applicant argues that "the principle" of the invention is proven, thus the invention is enabled. However, the theoretical possibility that an invention *could* be made is insufficient evidence that the Applicant was in possession of the invention as claimed. Further, while the invention may be enabled, the invention has not been adequately described.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-4 and 21 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by Tempest et al. (March, 1991, of record) for the reasons of record set forth in paper No. 9, mailed 4/26/00.

Applicant's arguments and a declaration by Dr. Leslie Johnson, filed 10/30/00, have been fully considered but they are not persuasive. Applicant argues that a declaration filed in Application No. 08/290,592 proves that Applicant conceived of, then diligently pursued the invention of the instant claims prior to March 1991. However, said declaration has been only partially submitted in the instant case and is thus not found convincing. Exhibit 1, assertedly demonstrating conception has been enclosed; Exhibits 2-4 assertedly demonstrating diligence have not been enclosed. Further, it is noted that Exhibit 1 fails to provide support for the conception of all the limitations of the invention of the instant claims. As claimed, the invention encompasses a human-murine chimeric antibody including one or more (claim 1) or three (claim 21) murine CDR's per light or heavy human Ig chain. Exhibit 1 discloses only Ig's in which "murine CDR's will be substituted into human heavy and light chain cDNA's," thus, Exhibit 1 discloses only the genus of human-murine chimeric antibodies and not the claimed subgenus's of human-murine chimeric antibodies comprising specific numbers of substituted CDR's.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4, 6-7 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tempest et al. (1991, of record) in view of Beeler et al. (1989, of record) for the reasons of record set forth in paper No. 9, mailed 4/26/00.

Applicant's arguments, filed 10/30/00, have been fully considered but they are not persuasive. Applicant argues that the Beeler et al. reference does not teach humanized antibodies. However, said reference has been combined with the Tempest et al. reference that does, thus, the rejection is proper.

9. Claims 1-4, 6-7, and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (1986, of record) in view of Beeler et al. (1989, of record) for the reasons of record set forth in paper No. 9, mailed 4/26/00.

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that the Jones reference does not teach: the substitution of CDR'S specific for RSV, the substitution of light chain CDR's, nor the value of humanized antibodies in human therapy.

Regarding the substitution of CDR'S specific for RSV, applicant is correct, the reference does not teach said specific substitution - the reference teaches the concept of the substitution of murine CDR's on a human antibody framework. As the rejection is however, based on obviousness in view of the Beeler et al. reference discussed supra, the rejection is proper. Regarding the substitution of light chain CDR's as well as heavy chain CDR's, the reference teaches that the concept of said substitution is valid for V_H, V_κ, as well as V_λ (V_κ and V_λ being light chains) thus said substitution would be obvious and the rejection is proper.

10. No claim is allowed.

11. Applicant's Terminal Disclaimer, filed 10/30/00, has obviated the previous nonstatutory double patenting rejections of claims 1-4, 7, and 21.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire

on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 8:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Patrick J. Nolan

G.R. Ewoldt, Ph.D.
Patent Examiner
Technology Center 1600
January 10, 2001

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600